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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,393	10/26/2001	Joel S. Hochman	Athena I	9804
30996	7590	12/16/2004	EXAMINER	
ROBERT W. BECKER & ASSOCIATES 707 HIGHWAY 66 EAST SUITE B TIJERAS, NM 87059			MARMOR II, CHARLES ALAN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,393

Applicant(s)

HOCHMAN ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2004 and 30 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 and 15 is/are allowed.
- 6) ☒ Claim(s) 1-13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after advisory action. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 5, 2004 has been entered.

The Examiner acknowledges the amendments to claims 1, 7, 9 and 14, as well as the addition of new claim 16. Claims 1-16 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "non-implanted" recited in line 4 of claims 1 and 16 renders the claim indefinite. No special definition of the term is set forth in the specification of the instant application. Therefore, one cannot be certain of the metes and bounds of this term, which is a negative limitation, and thus the scope of the aforementioned claims.

In the Tenth Edition of Merriam Webster's Collegiate Dictionary (1996), the verb "implant" is defined as "to insert in a living site." In view of this "dictionary" definition of the

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word "implant," the limitation "non-implanted," or essentially not inserted in a living site, used in the claims of the present invention would appear to contradict subsequent limitations of the claims that require the device to be inserted into and contained within the vagina in order to monitor vaginal conditions, and therefore render the claimed apparatus inoperable.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-7, 11-13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Guice et al. ('390). Guice et al. teach a system and method for monitoring the health and status of livestock and other animals. The system includes at least a single, separate unit **50,51,280** in the form of a portable, intravaginally containable combination probe, transceiver and power source and a single, separate unit **70,72** in the form of a combination controller and transceiver. The use of the transitional term "comprising" in the claim language is inclusive or open-ended and does not exclude additional, unrecited elements (i.e., in addition to the claimed two "single, separate units"). See MPEP 2111.03. The single, separate unit **50,51,280** in the form of a portable, intravaginally containable combination probe, transceiver (see at least paragraph [0124]) and power source **288** is "non-implanted" in a substantially equivalent sense as the limitation is defined in the specification of the instant application (i.e., "intravaginally

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containable... in situ yet removable" as recited in paragraph [0010]), although the patentee has chosen to call his telesensor an "implant." The Guice implant embodiments of Figs. 18 and 19 (see paragraph [0179]) are in the form of spring-like curved members that can be compressed to a smaller diameter to be inserted into a vaginal cavity, then expand to a larger diameter after being inserted into the vaginal cavity, and are provided with tabs 299 or a wire member 301 to aid in removal of the telesensor implant without the need for incisions or surgery. With regard to claim 16 of the present application, the limitation "said unit is non-expandable and non-compressible in cross-section" fails to define the present invention over the probes of Guice et al. since the application fails to define what cross-section of the unit is being limited. The probes of Guice et al. (Figures 17-19) are not disclosed as being expandable or compressible along the width of the outer surface of the housing. The combination probe, transceiver and power source of Guice et al. is provided with means for sensing vaginal conditions 292 and 2-way wireless communication means for transmitting information that is transduced and for receiving control and programming signals (see at least paragraph [0124]). The separate combination controller and transceiver is provided with wireless means for sending signals to the probe and for receiving signals therefrom (see at least paragraph [0209]). A wireless signal feedback loop is provided between the controller and the probe and which may be an interactive or closed signal feedback wireless loop. The probe is a sealed unit which is inserted "in-situ" into the vaginal vault or removed therefrom (see at least paragraph [0135]). The means for sensing vaginal conditions of the probe include sensor transducers 292 that may be provided with means for transducing in the form of a muscle activity sensor (see at least paragraph [0080]); means for sampling temperature changes (see at least paragraph [0106]) in the vaginal environment. The

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wireless combination controller and transceiver includes means for wirelessly altering operation settings of the probe and means for wirelessly altering the transducing sensor (see at least paragraph [0104]). A wireless means 72 is provided to transmit signals to and/or receive signals from external devices, networks, or databases. The controller may be inclusive of a hand-held unit (e.g., a PDA). The probes (Figs. 17-19) of Guice et al. are capable of being self-applied by a human subject into the human vagina such that vaginal conditions are transduced by the probe.

Allowable Subject Matter

6. Claims 14 and 15 are allowed over the prior art of record.
7. Claim 8-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
8. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 8-10, no prior art of record teach or fairly suggest a system, as claimed by Applicant, where the single, separate unit in the form of an intravaginally containable combination probe, transceiver and power source is provided with at least one of means for delivering medication to the vaginal vault and means for stimulating perineal musculature and nerves in combination with means for sensing or transducing vaginal conditions.

Regarding claims 14 and 15, no prior art of record teach or fairly suggest a method, as

claimed by Applicant, where a human subject inserts a portable, single separate unit in the form of a combination probe, transceiver and power source into said human's own vagina and uses the probe to transduce vaginal conditions, deliver signals or medication, or stimulate perineal musculature and nerves, and where a wireless signal feedback loop is provided between the probe and a separate unit in the form of a combination controller and transceiver that sends signals to and receives signals from the probe.

Response to Arguments

9. Applicant's request for the "withdrawal of the finality of the present Office Action" at page 7 of the Remarks filed November 5, 2004 is moot in view of the filing of the RCE simultaneously therewith.

10. Applicant's arguments filed November 5, 2004 have been fully considered but they are not persuasive. Applicant contends that the Guice probe must be implanted. Applicant argues that Guice characterizes his probe as an implant; that Guice probes are installed with special implant installation tools; that Guice allegedly teaches against the use of "non-implanted" devices in paragraph [0034]; that Guice's use of the terms "implant" and "installed" emphasize that his probes are implants; that "Guice's teaching leaves no question that his choice of the word 'implant' is a technical term of art which means that installation is required and furthermore is synonymous with the requirement to monitor animals continuously over extended periods of time;" and that Guice is explicit about the problems of 'implant drift' to support his position. Applicant further contends that the Guice probe is not "portable." Applicant argues that Guice's

requirements of "installation," "special tools" and "adhesives" in the installation procedure as well as Guice's modifications of loops, tabs, wire members and hooks do not support the issue of portability in order to support his position. Applicant further contends that Guice is intended for use in livestock and is not applicable to human use. Applicant finally contends that Guice in no way teaches the use of controllers, rather that the PDA's of Guice are merely data collection, data alert warnings or database devices.

Regarding Applicant's argument that the Guice probe must be implanted, the argument is not persuasive. Guice may call his probe "an implant;" however, Guice is entitled act as his own lexicographer and call his probe whatever that applicant may want. The Guice device nevertheless meets all of the structural limitations of at least apparatus claims 1 and 16 of the present application. The Examiner also notes that although Applicant repeatedly contends that Guice teaches away from "non-implanted" devices, Guice never uses the term "non-implanted" in any part of that application. Applicant alleges that paragraphs [0006], [0033], [0040], [0157] and [0161] of Guice teach disadvantages of "non-implanted" devices such as implant drift; however, Guice refers to these allegedly non-implanted devices as "implants" as well. Although Applicant contends that in paragraph [0034] Guice refutes the use of "non-implanted" devices, this argument is not fully accurate as said paragraph merely discusses some disadvantages or shortcomings of one particular patented apparatus, where that patent teaches against the use of implants. The Examiner contends that paragraph [0034] does not comprise a blanket teaching that all "non-implanted" devices are disadvantageous.

The Examiner points out that the "non-implanted" limitation can be considered as defining the intended use of the present invention. The Guice device is capable of performing

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this intended use as illustrated by the embodiment of Figures 18 and 19 where the Guice device is inserted into the vaginal cavity and is provided with tabs or a wire member to aid in subsequent removal of the Guice device from the vagina. Since the apparatus of the Guice patent meets all of the structural limitations of the claimed apparatus of the present invention, and is capable of being inserted intravaginally in a subject and subsequently removed, the Guice patent is considered to anticipate the present invention as claimed. Applicant appears to be attempting to rely on a special definition of the term "non-implanted" to define the present invention over the Guice apparatus. However, the Examiner points out that Applicant has failed to provide a special definition of the term "non-implanted" in the specification of the present application. Applicant merely states in the detailed description of the present application that the non-implanted device is "intravaginally containable... in situ yet removable" as recited in paragraph [0010] and claim 6. The Guice probes are intravaginally containable and "in situ yet removable." In the arguments filed November 5, 2004, Applicant provides several dictionary definitions of the word "implant" in an attempt to define what is meant by the limitation "non-implanted." However, this argument raises a new question of indefiniteness under 35 U.S.C. 112, second paragraph, set forth hereinabove, as the Examiner has found that in the Tenth Edition of Merriam Webster's Collegiate Dictionary (1996), the verb "implant" is defined as "to insert in a living site." In view of this "dictionary" definition of the word "implant," the limitation "non-implanted," or essentially not inserted in a living site, used in the claims of the present invention would appear to contradict subsequent limitations of said claims that require the device to be inserted into and contained within the vagina in order to monitor vaginal conditions. Applicant's assertion that Guice's use of the terms "install" and "installation"

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support that the Guice probe is an implant raises similar issues. In the American Heritage® Dictionary of the English Language, Third Edition (1992), the verb "install" is defined as "to set in position... or adjust for use" and "to settle in an indicated place or condition." In light of these definitions of the term "installed," if the probe of the present application was not also installed, it is not clear how the probe of the instant invention would arrive at the end condition of being contained intravaginally.

Applicant finally contends that the implants of Guice are in fact implants because they are required to monitor animals continuously over extended periods of time. Applicant points to paragraph [0010] of Guice and the FDA definition of the term "implant" to support this argument. The Examiner respectfully submits that while paragraph [0010] teaches that the cattle remain on the feedlot for 90 days to a year and must be monitored for that time, the paragraph does not teach that the same, single probe is used to monitor a subject for the duration of that time period. Also, since the Guice probe is removable, it would appear that the Guice probe would be capable of being removed after a period of less than 30 days should an observer choose to do so, without altering the ability of the probe to function properly. The Examiner also notes that the probe of the instant application is not inserted intravaginally and removed immediately, rather it may reside in the vaginal cavity for a period upwards of 15 minutes. Therefore, absent any special definition of the phrase "extended period of time," the probe of the instant invention may also be considered to reside intravaginally for an extended period of time.

Regarding Applicant's argument that the Guice probe does not support the "portable" requirement of the claims, the argument is not persuasive. The Examiner again notes that no special definition of the term "portable" is set forth by Applicant in the specification of the

present application. The American Heritage® Dictionary of the English Language, Third Edition (1992), defines the adjective "portable" to mean "carried or moved with ease." Since the probe of Guice can be inserted in a subject and carried by the subject as the subject moves about, without requiring any hardwired connection to an external control unit or hindering the movement of the subject in any way, the Guice probe reads on this limitation of the claims. It is unclear how the recitations of "installation," "special tools" and "adhesives" in Guice are contrary to the idea of portability as Applicant alleges. Nevertheless, the Examiner respectfully submits that these features are not required by all embodiments of the Guice probe as evident from at least paragraph [0042] of the Guice publication.

Regarding Applicant's argument that the Guice probe is restricted to animal use and is not suitable for use in humans, the argument is not persuasive. In response to applicant's argument, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In the instant application, the claims require that the probe be capable of being self-applied by a human subject into a human vagina, where the probe will perform at least one of the following functions: sensing vaginal conditions, delivering signals or medication, and stimulating perineal musculature and nerves. The Guice probe is disclosed as being formed of materials that are "non-hazardous (i.e., non-toxic... and not producing other harmful effects) to humans" (see lines 5-8 of paragraph [0156]). The Guice probes are further disclosed as being sized to be inserted in the ear canal, vagina and nostril of

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livestock (see paragraphs [0100], [0122], and [0130]). It is the Examiner's position that the dimensions of the human vagina fall somewhere between the dimensions of the vagina of a cow and at least one of the ear canal or nostril of a cow. Therefore, the Guice probes illustrated in Figs. 17-19 may be sized such that they are capable of being inserted in a human vagina.

Otherwise, there is nothing in the structure of the Guice probes that would prevent the probes from being inserted into the human vagina. In view of the foregoing, a human would be capable of inserting one of the Guice probes illustrated in Figures 17-19 into the vagina of said human whether or not it would be advisable to do so. Once disposed with a human vagina, a Guice probe would be capable of functioning properly to sense vaginal conditions, such as the temperature of vaginal walls or a general temperature within the interior of the vaginal cavity. Since the Guice probes meet all of the structural limitations of the claims and are capable of performing the intended use of the claims, the rejection of claims 1-7, 11-13 and 16 under 35 U.S.C. 102(e) as anticipated by Guice et al. are regarded valid.

Regarding Applicant's argument that Guice in no way teaches the use of controllers and that the PDA's of Guice are merely data collection, data alert warnings or database devices, this argument is not persuasive. The claim language requires only that the "controller" send signals to and receive signals from the probe. The control units and PDAs of Guice may send signals to the probe requesting data from the probe telesensor and the signals wirelessly alter the transducing sensor, at least by wirelessly adjusting the time at which the sensor will take the next measurement (see at least paragraph [0104]). Therefore, the control units and PDAs of Guice meet the limitations of the claims.

In view of the foregoing, Applicant's arguments that the probes taught by Guice et al. do not meet the "non-implanted" and "portable" requirements of the claims, nor the claimed intended use of being self-inserted by a human into the human vagina, are not persuasive. As such, the rejection of claims 1-7, 11-13 and 16 under 35 U.S.C. 102(e) as anticipated by Guice et al. is regarded valid and has been maintained.

11. The declarations under 37 CFR 1.132 filed November 30, 2004 are insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102 (e) based upon Guice et al. as set forth in the last Office action because:

The declarations refer only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness/non-anticipation is commensurate in scope with the claims. See MPEP § 716.

Moreover, the declarations provide the opinions of two "experts" in the field of Obstetrics and Gynecology, yet both declarations fail to set forth facts that sufficiently prove that the Guice implant units are not capable of use in a human. Both declarations attempt to point to several teachings from the Guice reference as evidence that the Guice implant units are not acceptable for human use and are not "non-implanted" devices. However, the teachings of Guice (e.g., the use of adhesives and tools to install the implant units) pointed to by Dr. Jayne and Dr. Wharton are not necessarily requirements of all embodiments of the Guice system as evident from the disclosure of paragraph [0042] of the Guice reference. The declaration of Dr. Jayne further repeatedly alleges that the "FDA standards and regulations and safety concerns" support

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that the implant units of Guice may not be used in a human vagina; however, the declaration still fails to provide factual evidence to support his position, such as the particular definitions of those “FDA standards and regulations and safety concerns” that Dr. Jayne refers to. The lack of factual evidence provided in the declarations of Dr. Jayne and Dr. Wharton render the declarations insufficient to overcome the rejection of claims 1-7 and 11-13 under 35 U.S.C. 102 (e) as anticipated by Guice et al.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of non-anticipation and nonobviousness fails to outweigh the evidence of anticipation.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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December 7, 2004